

REMARKS

In the Office Action dated December 29, 2005, the Examiner objected to claims 33-35 as being dependant on a rejected base claim, but indicated that claims 33-35 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicant thanks the Examiner, and has added new independent claim 49 and dependant claims 50 and 51, which include claims 33-35 with all the limitations of the base claim and any intervening claims. Claim 26 and claim 46 have also been amended in order to clarify the subject matter. Claims 1-25 have been withdrawn in response to a restriction requirement, as stated previously. After entry of this amendment, claims 26-46 and 49-51 will be pending. Applicants believe that no new matter is introduced by this amendment. All claims are believed to now be in condition for allowance. Applicant has also amended limited paragraphs in the specification to correct typographical errors.

The Examiner rejected claims 26-29, 36, and 37 under 35 U.S.C. 103(a) as being unpatentable over Newberg (U.S. Patent Number 5,296,197) in view of Witte (U.S. Patent Number 5,948,998); claims 30-32 and 39 under 35 U.S.C. 103(a) as being unpatentable over Newberg in view of Witte as applied to claim 27 and in further in view of Carney (U.S. 5,771,917); claim 38 under 35 U.S.C. 103(a) as being unpatentable over Newberg in view of Witte as applied to claim 27, in further view of Merten (U.S. 6,689,621); claim 40 under 35 U.S.C. 103(a) as being unpatentable over Newberg in view of Witte and Carney as applied to claim 39, and further in view of Merten (U.S. 6,689,621); claims 41 and 42 under 35 U.S.C. 103(a) as being unpatentable over Newberg in view of Witte, Carney, and Merten as applied to claim 40, and further in view of North, Jr. (U.S. 5,395,588); claims 43-45 under 35 U.S.C. 103(a) as being unpatentable over Newberg in view of Witte as applied to claim 26, and further in view of Gerard (U.S. 20020170364); and claim 46 under 35 U.S.C. 103(a) as being unpatentable over Newberg in view of Witte, Carney, Merton, and North, Jr. It is respectfully submitted that the rejection can not be properly applied to the amended claims and reconsideration is requested.

In order to reject a claim under 35 U.S.C. §103(a), the Office Action must first establish a *prima facie* case of obviousness. Establishing a *prima facie* case of obviousness requires that:

(i) there must be some suggestion or motivation, either in the reference or in the knowledge

generally available to one of ordinary skill in the art, to modify the reference; (ii) there must be a reasonable expectation of success; and (iii) the prior art reference must teach or suggest all of the claim limitations. *In re Vaeck*, 947 F2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Each of the Examiner's rejections will be addressed in the subsequent discussion.

Prior to addressing the Examiner's rejections, Applicant will describe an embodiment of the invention to provide insight into the claim though the claims are not limited to the embodiment and the description does not limit the claims. This embodiment can be better understood by referring to FIGS. 7B and 7C. A method of aseptically sampling a biofluid with the apparatus includes automatically collecting a biofluid sample by opening an inlet valve 703. The sample is automatically directed to the biofluid processing site 753 by opening an outlet valve 702, and closing a waste valve 704. The biofluid site is isolated by closing the inlet and outlet valves, and opening the waste valve to drain biofluid from a trap 715 which is a part of a sampling conduit 754. As can be seen, the waste valve is located at a low region of the trap. Finally, the sampling conduit is cleaned before sample collection by directing wash fluid through at least one valve selected from the inlet and outlet valves, and subsequently through the waste valve to the waste site.

An optional flow sensor 718 can be located at the sampling conduit 754 or waste conduit 756, preferably at the waste conduit between the trap and waste site 720. The flow sensor 718 can, for example, be employed to sense for back fluid flow, particularly when the biofluid is isolated. As used herein, "backflow" means undesirable fluid flow in the system, e.g., due to failure of valves 703 or 702 to close, and the like. Backflow can lead to cross-contamination, loss of valuable bioreactor fluid, and the like during isolation.

As stated, the Examiner rejected claims 26-29, 36, and 37 under 35 U.S.C. 103(a) as being unpatentable over Newberg in view of Witte. Newburg describes an apparatus for withdrawing a sample from a vessel or conduit, where the apparatus includes a main body with an inlet passage and a drain passage. As described by the Examiner, a biofluid sample is collected by opening an inlet valve at a biofluid source site. The sample can then be directed to a biofluid process site by opening an outlet valve coupled to a process site. A waste valve is coupled to a sampling conduit and the waste valve is closed in order to move the sample to the process site. Steam, pure dry air or a wash medium can be provided through the inlet passage to cleanse the apparatus.

Witte discloses a sampling device for taking sterile samples of a fluid from a fermentor or bio-reactor. The device includes a holder in fluid communication with the fermentor for removably connecting sample collecting containers. An adaptor is removably connected to the holder for steam sterilization of the holder between collection of successive samples.

The Examiner stated that Newberg does not disclose a trap located at the sampling conduit and fluidly connected to the waste valve. The Examiner also stated that Witte discloses a trap that is in connection with the sampling conduit and in fluid communication with a waste site. For reference, Examiner refers to Figure 1:36. Witte explicitly describes the trap as a steam trap. (Col. 1, lines 36-64). The purpose of the steam trap as described, is to collect steam during sterilization of the apparatus.

Claim 26 has been amended to clarify the location of the trap. As stated in amended Claim 26, the trap is “a portion of the sampling conduit extending from the inlet valve to the outlet valve, and the waste valve is coupled to a low region of the trap.” As disclosed by Witte in Figure 1, the steam trap is not a portion of the sampling conduit, and the sample does not flow through the trap.

Additionally, the Examiner stated that “Witte teaches that it is useful to transport biofluids through the valve and conduit system in order to drain the biofluid to a waste discharge.” The Examiner referenced Witte’s Figure 2:62. As described by Witte, 2:62 refers to a waste discharge site (Col. 4, lines 19-34) As seen in Figure 2, the waste discharge site is located much above the sample container 2:60. As stated previously, Applicant’s amended claim 26 states that the trap is a portion of the sampling conduit, and that the waste valve is coupled to a low region of the trap. Witte discloses a steam trap, which can be connected to the apparatus for sterilization purposes before and after the sample has been collected. Additionally, the waste discharge is not a portion of the sampling conduit, or in this case the sample container holder 2:60; nor is the waste discharge coupled to a low region of the trap.

The combination of Newberg and Witte, therefore, does not teach or suggest all of the claim limitations of independent claim 26. Thus, Examiner does not meet the prima facie case of obviousness under 35 U.S.C. §103(a).

Rejected dependant claims 27-29, 30-32, 36, 37, 38, 39, 40, 41, 42, and claims 43-45 are all dependant on base claim 26, and therefore include all of the limitations of the amended base

claim. For the reasons stated regarding the 103(a) rejection of claim 26, the combination of Newberg and Witte, along with any other reference cited by Examiner, does not teach or suggest all of the claim limitations of dependant claims 27-29, 30-32, 36, 37, 38, 39, 40, 41, 42, and claims 43-45. Thus, the Examiner does not meet the prima facie case of obviousness under 35 U.S.C. §103(a) for these claims.

The Examiner also rejected independent claim 46 under 35 U.S.C. 103(a) as being unpatentable over Newberg in view of Witte, Carney, Merton, and North, Jr. Claim 46, like claim 26, has been amended to clarify the location of the trap. As stated in claim 26, the trap is a portion of the sampling conduit extending from the inlet valve to the outlet valve, and a waste valve is coupled to a low region of the trap. For the reasons described in the 103(a) rejection discussion of claim 26, the combination of Newberg, Witte, and other references cited by Examiner fail to teach or suggest all of the claim limitations of independent claim 46. In particular, the combination of these references do not teach a trap which is part of a sampling conduit, and a waste valve coupled to a low region of the trap. Thus, Examiner does not meet the prima facie case of obviousness under 35 U.S.C. §103(a) for amended claim 46.

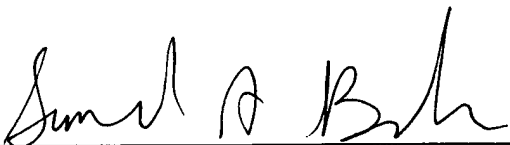
Accordingly, Applicants submit that claims 26, 27-29, 30-32, 36, 37, 38, 39, 40, 41, 42, claims 43-45, and claim 46 are not obvious in view of the prior art because the Office Action had not established a prima facie case of obviousness for these claims. Applicants respectfully request that Examiner reconsider and withdraw the §103(a) rejection of these amended claims.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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